Health Canada
Pest Management Regulatory Agency

Santé Canada
Agence de réglementation de la lutte antiparasitaire

Guidance Document for the

Pest Control Products Incident Reporting Regulations

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Canada

FOREWORD

Guidance documents are meant to provide assistance to registrants and interested stakeholders on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document **may be** acceptable provided they are supported by adequate scientific justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

This document is intended to be used in conjunction with the Pest Control Products Incident Reporting Regulations (IRR). It is not to be considered a substitute for the IRR or a stand alone document.

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1 INTRODUCTION

Pest control products (pesticides) are regulated in Canada under the federal *Pest Control Products Act* (PCPA). A new PCPA came into force on June 28, 2006.

Under the PCPA, a pesticide must be registered by the Minister of Health before it can be used in Canada. Health Canada's Pest Management Regulatory Agency (PMRA) administers the PCPA on behalf of the Minister. A pesticide may not be registered or may not continue to be registered unless its health and environmental risks and its value have been determined to be acceptable by the Minister.

Although pesticides are tested and evaluated for safety before they are registered, some adverse effects may not become evident until the product is used under "real-life" circumstances. One of the new provisions of the new PCPA (section 13) is the requirement for registrants, and applicants for the registration of a pesticide, to report incidents of adverse effects that involve their pesticides. Requiring registrants to submit incident reports contributes to the PMRA's ongoing collection of safety information that occurs once products are marketed.

Incident reports will provide the PMRA with valuable information regarding potential risks to humans or the environment from the "real-life" use of pesticides. If evaluation of this information identifies a safety issue, appropriate action will be taken. Such action could range from minor label changes to discontinuation of a product.

While the PCPA provides the PMRA the authority to require mandatory reporting, the Pest Control Products Incident Reporting Regulations (IRR) specify the actual reporting requirements, including the types of information to be reported and the time frames for reporting the information. Under these Regulations, registrants and applicants are required to report information concerning incidents that occur in Canada or the United States (U.S.) or that are identified in scientific studies.

Incidents include effects on humans, domestic animals or the environment, packaging failure that could result in human exposure or injury, and excessive residues in food. An incident that results from an act or activity that would constitute an offence under the *Criminal Code* is not included under the IRR.

The following guidance document is intended to provide further explanation of some sections of the Regulations. It is not to be considered comprehensive. A copy of the Regulations can be obtained from the PMRA website (www.pmra-arla.gc.ca).

2 GENERAL

The following is relevant to all IRR sections:

- An incident must be reported whether the suspected substance is the active ingredient, another component or a derivative of the pest control product.
- The requirements prescribed in the IRR apply to registrants of pest control products and applicants for the registration of pest control products. In this guidance document, the term “registrant” will be used to indicate registrants and applicants unless otherwise noted.
- Reporting an incident under these Regulations does not exempt the responsibility of the registrant to report under other Acts or regulations.

2.1 Who is required to report incidents?

Registrants of pest control products and applicants for the registration of pest control products are required to report pesticide incidents.

2.1.1 Foreign registrants

Foreign registrants must designate a representative who resides in Canada (subsection 62 (2) of the PCPA). Under section 13 of the PCPA the obligation to submit incident reports rests with the registrant, however, if the registrant chooses, they may submit incident reports through their representative instead. If the representative fails to properly carry out the registrant's obligation, any action taken by the Minister will be against the registrant, not against the representative.

3 INTERPRETATION

3.1 What is an incident (*subsection 1(1) of the IRR*)?

In the IRR, incident means an incident whose effects relate to the health or environmental risks or the value of a pest control product. If the substance alleged to be responsible for the incident is the end-use product, active ingredient, other component contained within the product or a derivative of the product, it is considered to be related to the health or environmental risks or the value of the pest control product. Registrants must report an incident if it meets the conditions of one or more of the categories described in section 2 of the IRR and it involved their pest control product. The incident categories are: effects on humans, domestic animals or the environment; packaging failure that could result in human exposure or injury; excessive residues in food; and effects identified in scientific studies.

3.1.1 What is excluded under the definition of “incident”?

An incident does not need to be reported if it results from a criminal activity as defined in the *Criminal Code*.

3.2 What is an incident report (*subsection 1(1) of the IRR*)?

An incident report is a report that contains the information a registrant must submit. Under section 13 of the PCPA, the Minister can direct the form and manner for reporting incidents. Consequently, registrants must use the PMRA incident reporting forms when submitting an incident to the PMRA. In addition, the report must be submitted electronically. Guidance on how to complete the reporting forms is provided on the PMRA website.

3.3 Are registrants required to investigate the information they receive (*subsection 1(2) of the IRR*)?

When registrants report incidents to the PMRA, they are not required to prove or substantiate the information. They are required to accurately complete the mandatory reporting forms based on the information provided to them. Relevant supplemental information such as opinion or commentary, as explained in Chapter 11.1.2, can also be provided.

4 CLASSIFICATION OF INCIDENTS *(section 2 of the IRR)*

4.1 Human and domestic animal incidents (*paragraphs 2(a) and 2(b) of the IRR*)

Human and domestic animal incidents are classified using the same criteria. There are four severity categories: death, major, moderate and minor. The type of symptoms, duration of the symptoms and any required medical treatment will assist registrants in the classification of incidents. If an incident meets the criteria for more than one severity category, classification should be based on the most severe of the categories. For example, if reported symptoms are included on the minor severity list but medical treatment was required, the incident would be classified as moderate. As another example, if 2 of the symptoms for the incident are minor and the third symptom is major, the incident would be classified as major. A list of symptoms categorized by severity is provided in Appendix A. This list was developed to classify the severity of human and domestic animal incidents, as such, some symptoms may not be relevant to both types of incidents. If a symptom is not on the severity list, refer to the definitions of minor, moderate and major in the Regulations.

The criteria listed below in Chapters 4.1.1 to 4.1.4 are to be used as a guide to help registrants determine the severity level of a human or domestic animal incident. Other factors, such as the intensity of the symptom and the presence of other symptoms should also be considered when classifying the incident. As such, a different classification of the severity of the incident could be acceptable if it is based on clinical judgement and a rationale is provided. A decision tree of the criteria is provided in Appendix B.

4.1.1 Minor

Minor incident: minimally bothersome symptoms that normally resolve rapidly, such as skin rash, itching, drowsiness, headache, restlessness or diarrhea. Typically the symptoms resolve without treatment. A human or domestic animal incident is categorized as minor if all of the following criteria are met:

i) the symptom is categorized as minor (see Appendix A);
ii) professional medical treatment was not provided; and
iii) the symptom lasted for less than 1 month.

4.1.2 Moderate

Moderate incident: symptoms that are more pronounced, more prolonged or of a more systemic nature than minimally bothersome symptoms, and for which some form of treatment is usually required, although the symptoms do not indicate a life-threatening condition and the person or animal is likely to return to their pre-exposure state of health without any chronic disability. A human or domestic animal incident is categorized as moderate if any of the following criteria are met:

i) the symptom is categorized as moderate (see Appendix A);
ii) if hospitalized, stay was 72 hours or less; or
iii) the symptom lasted for less than 6 months.

4.1.3 Major

Major incident: symptoms that indicate a condition that could be life-threatening or result in adverse reproductive or developmental effects or in chronic disability. This level of effect commonly involves hospitalization and might include the need for continued health care and limitations or modification of normal activities. The person or animal may sustain permanent functional impairment. A human or domestic animal incident is categorized as major if any of the following criteria are met:

i) the symptom is categorized as major (see Appendix A);
ii) hospitalization stay was greater than 72 hours; or
iii) the symptom lasted for 6 months or more.

4.1.4 Death

If a domestic animal is euthanised as an outcome of the incident, the incident would not be classified as subparagraph 2(b)(i) ‘domestic animal death’. Instead, it’s classification would be either minor, moderate or major based on the severity and duration of the symptoms and requirement of medical treatment as discussed above. ‘Euthanised’ would be indicated as the outcome on the incident report.

4.1.5 Definitions of "medical treatment" and "hospitalization"

For the purpose of these Regulations, "medical treatment" includes any medical intervention, whether it is medication or physical treatment, prescribed or provided by a medical professional. It can include prescription medication, over the counter medication, physiotherapy, etc. If a data subject visits a medical professional, such as a physician or a nurse, but does not receive any form of medical intervention, they would not be considered to have received medical treatment. Similarly, a person is hospitalized if they have been admitted to a hospital as an inpatient. Treatment at a hospital as an outpatient is not considered hospitalization.

4.2 Environment incidents (*paragraph 2(c) of the IRR*)

An incident in the environment is classified based on the number of individuals that are affected, the symptoms, whether it was a species at risk that was affected and, in the case of plants, the number of incidents reported in a given time frame. There are three severity categories: major, moderate and minor. The definitions for the categories for incidents in the environment are in paragraph 2(c) of the IRR. These definitions must be used in conjunction with the schedule in the IRR to determine the severity category of the incident.

The schedule specifies the criteria (number of organisms affected, symptoms and any other conditions) for the different severity categories for each type of organism with the exception of a species at risk. There are 10 different groups of organisms in the schedule (birds, amphibians, mammals, reptiles, fish, aquatic invertebrates, terrestrial invertebrates, trees and shrubs, herbaceous plants, and aquatic plants), some of which are further divided into subgroups (e.g. predatory birds and songbirds) (see Appendix C for definitions and examples). The criteria for major, moderate and minor effects are different for each group or subgroup of organisms. If an incident involved animals or plants from multiple groups or subgroups, a severity category would be assigned for each group or subgroup. If it involved multiple species of organisms from the same group or subgroup it would be assigned one severity category.

In general, the severity categories are based on the number of organisms affected within a group or subgroup and the type of symptoms. However, the diversity of organisms and their associated ecologies in each taxonomic group is very wide, making it challenging to develop categorizations for severity based solely on numbers of organisms affected in a given group; therefore, in some cases, temporal and spatial factors have been included. For example, one of the criteria for a moderate effect in herbaceous plants is that the incident occurred within the targeted spray area or within 20 m of its edge.

If an incident meets the criteria for more than one severity category, classification should be based on the most severe of the categories. Incidents in the environment refer to non-target organisms only. Effects on plants or animals which were the target of the pesticide application are not required to be reported. Definitions of environmental symptoms are provided in Chapter 13 of the guidance document.

4.2.1 Major

Except for species at risk, an incident is classified as major if the symptom is death and the number of organisms that die is at least the number set out in column 3 of the schedule. For example, if an incident involved 32 squirrels (small mammals) but only 10 died and the remainder exhibited other effects, it would be classified as moderate. If 30 of the squirrels had died, it would be classified as major. The groups terrestrial invertebrates (except honey bees), trees and shrubs, herbaceous plants and aquatic plants do not have a major category, only minor and, for the plant groups, moderate. For honey bees, an incident is classified as major if 3,000 bees from each of 5 or more colonies (for a total of 15,000 bees) have died or 30% of the bees in any one colony.

If the organism(s) affected is a species at risk, as defined by the *Species at Risk Act*, the incident is classified as major even if only one organism was affected. In addition, for a species at risk, the symptom can be any one of the symptoms listed in column 6 of the schedule for it to be classified as major, it does not need to be death. Grizzly bears (Ursus arctos; Prairie population) are classified as an extirpated species in the *Species at Risk Act*. As such, if one Prairie grizzly bear exhibited health effects as a result of pesticide exposure, the incident would be classified as major. In contrast, if the incident involved a black bear, which is not a species at risk, it would be classified as minor. An incident involving black bears would only be classified as major if at least 15 animals died.

4.2.1.1 Species at risk (*clause 2(c)(i)(B) of the IRR*)

According to the *Species at Risk Act*, species at risk means an extirpated, endangered or threatened species or a species of special concern. Refer to the List of Wildlife Species at Risk in Schedule 1 of the *Species at Risk Act*. The Act can be found on the Department of Justice of Canada website (www.canada.justice.gc.ca), under ‘Laws’.

4.2.2 Moderate and minor

For moderate and minor effects, the organisms could experience any of the symptoms listed in column 6 of the schedule for that group or subgroup and different organisms could have different symptoms. For example, a moderate effect in birds that flock could include 30 dead ducks and 30 geese exhibiting immunosuppresion.

4.2.2.1 Plant groups

Plant groups have two categories: minor and moderate. A single incident involving any plant group is classified as minor regardless of the number of plants affected. A moderate effect in plants depends on the number of incidents reported in a given time frame. For example, for trees and shrubs, a single incident would be classified as minor, however, if 5 incident reports for the same active ingredient were received by a registrant within one month, and at least 25 trees or shrubs were affected in each incident, all 5 incidents would be classified as moderate. The trees or shrubs do not need to be the same species and the 5 incidents do not

need to occur in the same location. More than 25% of the tree or shrub must be affected by one of the symptoms in column 6 of the schedule for the incident to be classified as minor or moderate.

A moderate effect for herbaceous plants is when, similar to trees and shrubs, there are 5 or more reports sent to the registrant for 1 active ingredient within the same month and a) 25% or more of the non-target plants within the targeted sprayed area are affected, or b) 25% or more of the plants outside of the targeted spray area are affected. The 20 m border outside of the targeted spray area does not include the buffer zone. The buffer zone is within the target area. Therefore, if a target spray area has a 10 m buffer zone, the 20 m border begins outside of the buffer zone.

Incidents involving aquatic plants would be classified as moderate when there is 5 or more reports (for 1 active ingredient received within 1 month) and for each report at least 25% of the aquatic plants (e.g., water lilies) within the body of water experienced death, abnormal plant stance or abnormal leaf discolouration.

4.3 Residues in food (*paragraph 2(d) of the IRR*)

Pesticide residues in food must be reported if, as per paragraph 4(d) of the *Food and Drugs Act*, the amount of residue would result in the food being considered adulterated, prohibiting its sale. If the concentration of the pesticide, or any of its components or derivatives, in food exceeds the maximum residue limit, the food is considered adulterated and the information is reportable to the PMRA under the IRR.

For a definition of adulterated and a table of pesticide maximum residue limits, refer to section B.15.002 and Table II, respectively, in Division 15 of Part B of the Food and Drug Regulations. The Regulations can be found on the Department of Justice of Canada website (www.canada.justice.gc.ca), under ‘Laws’.

4.4 Packaging failure (*paragraph 2(e) of the IRR*)

Registrants are required to report incidents where the packaging fails to contain the product and that failure may lead to human exposure or injury. This is limited to incidents of packaging failure that occur during the normal use and storage of the product. Examples of packaging failure that are reportable include water soluble packaging degrading before being added to the tank or, a container that explodes during proper storage. Incidents of packaging failure that occur in situations outside of the normal storage and use of a product, such as a case of product falling off a truck during loading, are not required.

4.5 Scientific studies (*paragraph 2(f) of the IRR*)

Under paragraph 2(f), registrants must provide a scientific study they have **sponsored** if it indicates either a new health or environmental hazard, increased health or environmental risk or the presence of a component or derivative that has not been previously detected. In

addition to concluded studies, this requirement also includes studies that are ongoing or discontinued before completion if they indicate an adverse effect.

1) A new health or environmental hazard or increased risk is relative to what had been determined at the time of registration.

A) Studies must be submitted if toxicological effects occur:

- at a higher incidence or frequency
- at a lower dosage
- after a shorter exposure period
- after a shorter latency period
- in a different organ or tissue of the test organism
- in a different species, strain, sex, or generation of test organism
- by a different route of exposure

B) It also includes:

- an exposure monitoring study that indicates higher levels of risk or exposure than would be expected based on previously available reports, data, or exposure estimates
- a study indicating a previously undetected toxicological end-point such as a neurotoxic effect or positive response in genotoxicity assay
- a study indicating the concentration of the pesticide, or any of its components or derivatives, in food exceeds the maximum residue limit

C) Environmental studies of the toxicity of a pesticide to terrestrial or aquatic wildlife or plants must be submitted if, relative to all previously submitted studies, they show an adverse effect under any of the following conditions:

- At levels 50 percent or more lower than previous **acute** toxicity studies with similar species, including determinations of the median lethal dose (LD50), median lethal concentration (LC50), or median effective concentration (EC50).
- At lower levels in a **chronic** study than previous studies with similar species.
- In a study with a previously untested species the results indicate the chronic no observed effect level (NOEL) is 10 percent or less of the lowest LC50 or LD50 for a similar species.
- For plants when tested at the maximum label application rate or less, if:
  (i) More than 25 percent of terrestrial plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigour, reproduction and yields.
  (ii) More than 50 percent of aquatic plants show adverse effects on plant life cycle functions and growth such as germination, emergence, plant vigour, reproduction and yields.

2) Subparagraph 2(f)(iii) is not limited to detection of a new component or derivative but also includes presence of a component or derivative at a level higher than that determined at the time of registration.

For the purpose of these Regulations, “sponsored” means that the registrant contributed to the research, whether the contribution was financial or an ‘in kind’ contribution. In some way, the registrant occasioned the research.

5 PRESCRIBED INFORMATION: WHAT MUST BE REPORTED

5.1 What is “prescribed information” (*section 3 of the IRR*)?

According to section 13 of the PCPA, registrants must report any prescribed information they receive. The prescribed information listed in section 3 of the Regulations is the information that registrants must provide when reporting an incident. This is also the basis of the questions on the mandatory Incident Report form. By answering the questions on the form, registrants are providing the prescribed information. See the reporting form for further details.

5.1.1 Questions on the Incident Report form that are not "prescribed information"

There are two questions on the form that are not aimed at collecting prescribed information. These questions are where registrants can provide their own opinion about the incident. Registrants are not required to answer them but any information provided will be posted on the electronic public registry (see Chapter 11). The questions are:

1) "In your opinion, was the product used according to the label instructions?" (question 12, subform I: General information); and
2) "Provide supplemental information here." (last question on subforms II - VII). See Chapter 11.1.2 of this document for a definition of supplemental information.

5.1.2 What is'test data' (*Paragraph 3(2)(e) of the IRR*)?

In paragraph 3(2)(e) "test data generated" includes methodology, results (including raw data) and any discussion/conclusions.

5.2 What is the minimum amount of information in order for an incident to be reportable?

All of the information described in section 3 of the Regulations or on the reporting forms is prescribed information. However, two elements of prescribed information are required in order for an incident to be reportable to the PMRA: 1) the identification of the pest control product; and 2) information about the incident and its effects (paragraphs 3(1)(e) and (i) and 3(2)(c) and (e)). Identification of the pest control product could be the end-use product or active ingredient. Any additional prescribed information the registrant receives must also be reported.

5.3 What are registrants required to do with prescribed information they receive after an incident has been sent to the PMRA?

Any additional information the registrant receives after the incident report has been sent to the PMRA and that is considered prescribed according to section 3 of the IRR must be submitted to the PMRA. The time frame for submitting this information is based on the severity category of the report. If the additional information results in a change in severity category, it should be submitted in the time frame based on the new category. For example, if a report classified as domestic animal major was submitted to the PMRA and, after which, the registrant received information that the animal had died, that new information would need to be submitted to the PMRA within the time limit for domestic animal death (1 month).

6 GENERAL REQUIREMENTS

6.1 What is a "related corporation" (*paragraph 4(1)(b) of the IRR*)?

In addition to information received by a registrant, information received by a related corporation, regardless of where the related corporation is located, must also be submitted to the PMRA by the registrant within the appropriate time limit. Related corporation is used within the meaning of "related persons" as defined in subsection 251(2) of the *Income Tax Act*.

Income Tax Act definition of "related persons":
251 (2) For the purpose of this Act, "related persons", or persons related to each other, are
(a) individuals connected by blood relationship, marriage or common-law partnership or adoption;
(b) a corporation and
(i) a person who controls the corporation, if it is controlled by one person,
(ii) a person who is a member of a related group that controls the corporation, or
(iii) any person related to a person described in subparagraph 251(2)(b)(i) or 251(2)(b)(ii); and
(c) any two corporations
(i) if they are controlled by the same person or group of persons,
(ii) if each of the corporations is controlled by one person and the person who controls one of the corporations is related to the person who controls the other corporation,
(iii) if one of the corporations is controlled by one person and that person is related to any member of a related group that controls the other corporation,
(iv) if one of the corporations is controlled by one person and that person is related to each member of an unrelated group that controls the other corporation,
(v) if any member of a related group that controls one of the corporations is related to each member of an unrelated group that controls the other corporation, or
(vi) if each member of an unrelated group that controls one of the corporations is related to at least one member of an unrelated group that controls the other corporation.

6.1.1 Exception for scientific studies (*subsection 4(2) of the IRR*)

If a scientific study is received by a related corporation, the registrant is given an additional year to report that information. For example, a study received by a related corporation in May, 2007 must be submitted to the PMRA by the registrant before the end of June, 2008.

6.2 Reporting requirements after a transfer of registration (*section 5 of the IRR*)

The IRR requirements continue to apply to a former registrant for 5 years after the transfer of registration. Product with old labels containing contact information for the former registrant may continue to be available on the market for several years after the transfer. As such, the former registrant may continue to receive incident reports after the registration has been transferred. These reports must be submitted to the PMRA.

6.3 Language of reports (*subsections 6(1) and 6(2) of the IRR*)

Incident reports must be filed in English or in French. If translation of a scientific study cannot be completed within the reporting time limit, the registrant must request an extension and submit a summary of the document in English or in French within the prescribed time frame. The summary should be attached to the mandatory reporting form and must not be longer than one page.

7 REPORTING REQUIREMENTS

7.1 General reporting requirements (*sections 7, 8 and 9 of the IRR*)

Registrants are required to provide a complete and accurate report of any prescribed information they receive. They are not to alter or omit any of the prescribed information they have received when they report the incident to the PMRA. As explained in Chapter 3.3 of the guidance document, registrants are not required to substantiate or investigate the incident.

7.2 Incidents that occur in the United States (*section 8 of the IRR*)

Registrants are required to submit reports of incidents that occurred in the U.S. if the pesticide alleged to be responsible is related to one of their Canadian products and the incident was human death, a major effect in a human or domestic animal death. A U.S. product would be considered related to a Canadian product if it contained the same active ingredient. The formulation, use pattern or pest species do not need to be the same.

Incidents that occur in the U.S. may be submitted to the PMRA according to the time limits in the U.S. *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA), section 6(a)(2).

8 REPORTING TIME LIMITS

8.1 General

The time limits provided are the maximum amount of time in which a registrant must submit an incident report to the PMRA. Incident reports, particularly for the more serious effects, should be submitted as soon as possible within the time limit. Incidents that occur in the U.S. can be submitted to the PMRA according to the U.S. EPA time limits as specified in section 6(a)(2) of FIFRA.

8.2 15 Days (*section 10 of the IRR*)

All incidents listed under section 10 of the IRR that are received by the registrant must be sent to the PMRA within 15 days.

8.3 Monthly reports: one month accumulation, one month to report (*subsection 11(1) of the IRR*)

All incidents listed under subsection 11(1) of the IRR that are received by the registrant within a given month must be sent to the PMRA before the end of the next month. For example, all incidents that have a moderate effect in a human received by the registrant in the month of May must be reported to the PMRA before the end of June.

8.3.1 When a study has already been submitted to the PMRA (*subsection 11(2) of the IRR*)

If a scientific study has already been submitted to the PMRA for an application of registration or amendment without reporting the incident it contains, the registrant must submit an incident report indicating that the study has already been submitted, the submission number and date submitted. In this case, the study does not need to be submitted with the report form.

8.4 Quarterly reports: 3 months accumulation, 2 months to report (*section 12 of the IRR*)

All incidents listed under section 12 of the IRR that are received by the registrant are to be accumulated in a three month period (reporting period) and sent to the PMRA before the end of the second month following the reporting period (filing date). The time frame for the reporting periods and filing dates are specified in the table below. For example, all incidents of domestic animal death that occur in the U.S. or major effects in a domestic animal that are received by a registrant between January 1 and March 31, 2007 must be sent to the PMRA by May 31, 2007.

Reporting Period	Filing Date
January 1 to March 31	May 31
April 1 to June 30	August 31
July 1 to September 30	November 30
October 1 to December 31	February 28, or February 29 in the case of a leap year

8.5 Annual reports: 12 month accumulation, 2 months to report (*section 13 of the IRR*)

The accumulation period for incidents listed in section 13 is 12 months and the report(s) are sent to the PMRA at the end of the second month following the accumulation period. The dates for the accumulation period are staggered throughout the year based on the first letter or number of the registrant's name. The accumulation period for each registrant and when they must send the report(s) are specified in section 14 of the IRR. The date by which the registrant must send the incidents listed in section 13 is also the date the annual summary must be sent.

8.6 Date to file annual report(s) and annual summary (*sections 14 and 15 of the IRR*)

The date on which annual report(s) and the annual summary are to be submitted is based on the alphabetical distribution of registrants' names. See table for reporting dates. This will remain the reporting date for that registrant every year even if their name changes. If there is a merger of two or more companies, the annual report for the new company must be submitted to the PMRA on the earliest reporting date of the two companies original reporting dates. When the Regulations come into force, the first series of annual reports and the annual summary may have less than a 12-month accumulation period for some registrants, depending on their reporting date.

First letter or number of registrant name	Reporting period (accumulation of incidents to be reported)	Date to file incident reports that have been accumulated and annual summary
A or a number	December 1 to November 30	January 31
B	January 1 to December 31	February 28 or February 29 in the case of a leap year
C	February 1 to January 31	March 31
D	March 1 to February 28 or February 29 in the case of a leap year	April 30
E, F, G	April 1 to March 31	May 31
H, I, J	May 1 to April 30	June 30
K, L	June 1 to May 31	July 31
M	July 1 to June 30	August 31
N	August 1 to July 31	September 30
O, P, Q, R	September 1 to August 31	October 31
S	October 1 to September 30	November 30
T, U, V, W, X, Y, Z	November 1 to October 31	December 31

9 ANNUAL SUMMARY

9.1 Under what conditions is an annual summary required (*subsection 15(1) of the IRR*)?

Registrants are required to submit an annual summary for each active ingredient for which they have received 10 or more reports of incidents within that reporting period.

9.2 What should be included in the annual summary (*subsection 15(2) of the IRR*)?

Registrants must submit two parts for the annual summary; the number of incidents reported within that reporting period, including U.S. incidents, and a concise critical analysis of the incidents associated with their pest control products. Below is an example of a format that could be used to indicate the number of incidents reported in a given year.

Active Ingredient	Product Name	Number of Incidents per Category From June 1, 2007 to May 31, 2008								
		Human		Domestic Animal			Environment			Total per active
		minor	moderate	minor	moderate	death	major	moderate	minor	
Active Ingredient A	Product A	3	1							
	Product B			11	1	2				
	Total	3	1	11	1	2				18
Active Ingredient B	Product not known	2	5				1	1	5	
	Product D	1								
	Product E	2								
	Total	5	5				1	1	5	17

For the critical analysis, the registrant must provide:

i) a comparison with the number of incidents reported for that active ingredient in previous years and possible explanations for any differences observed;

ii) an explanation of any potential new or increased risks that have been observed including possible reasons for the occurrence of the incidents and probability of re-occurrence;

iii) a list of possible methods to mitigate the new or increased risks, and a discussion of the potential effectiveness and feasibility of each mitigation strategy. Include an implementation plan for the selected mitigation strategy. Examples of mitigation strategies are: adding chemical resistant gloves to the label, change in packaging, increase buffer zone, add a pre-harvest interval, etc; and

iv) a list of the PMRA incident report numbers for each incident referenced in the annual summary.

9.3 Date to file annual summary

See Chapter 8.6.

10 RECORDS

10.1 What information must registrants keep for 6 years and submit to the PMRA on request (*section 17 of the IRR*)?

The registrant must keep a record of every completed incident report and any information they have that relates to or is in connection with that report for 6 years. Information that the registrant may collect and that is not included in the report but that relates to the report could include: contact information of caller, contact information of the data subject (if not the caller), etc.

11 PLACEMENT IN THE PUBLIC REGISTRY

11.1 What will be posted in the electronic public registry and when (*subsections 18(1) and (2) of the IRR*)?

All incident reports that relate to registered pest control products, including supplemental information received from the registrant, will be placed in the Register and, subsequently, on the electronic public registry (PMRA website). The only information that will not be placed in the electronic public registry is personal information as defined by the *Privacy Act* (Chapter 16), confidential test data and confidential business information (Chapter 11.1.3). All confidential test data and confidential business information should be provided in an attachment to the report, not in the body of the incident report itself. Attachments will not be posted on the electronic public registry.

To protect privacy, the data fields city and province for human incidents and the names of authors of scientific studies will not be placed on the electronic public registry. In addition, although we strongly advise registrants not to provide any unrequested personal information, in the event it should occur, it will not be posted.

The electronic public registry will provide clear guidance on how to use the information provided in incident reports and explain that they are only allegations, they have not been substantiated or verified.

11.1.1 What are considered “reports that relate to registered pest control products”?

In addition to registrants, applicants for the registration of pest control products are also required to report incidents that relate to their products. As such, the PMRA may receive incident reports involving active ingredients that are under review at the PMRA for registration, but are not yet registered. Most likely, these would be incidents that occurred in

the U.S., during research, or in a scientific study. However, as stated in the Regulations, only incident reports that relate to a **registered** product will be posted on the electronic public registry. If the active ingredient involved in the incident is not registered, the report will not be posted. If the active ingredient is registered, the report will be posted, even if the end-use product involved in the incident is not registered.

It is the applicants responsibility to indicate if the active ingredient is not registered by providing the submission number of their application on the Incident Report form (Subform I: General Information, question 7a). If a submission number is not provided, the PMRA will assume the active ingredient is registered and will post the report.

11.1.2 What is considered "supplemental information" (*subsection 18(1) of the IRR*)?

Subsection 18(1) of the IRR states that the PMRA will post in the Register "supplemental information in support of the reports that is volunteered by the registrant or applicant, such as any relevant opinion or commentary." Supplemental information is any information the registrant considers relevant and that explains the circumstances or interprets the significance of the incident report.

Supplemental information can be included on the incident report form in the place indicated. It is within this space that registrants can describe why the pesticide was or was not the likely cause of the reported incident.

11.1.3 Confidential test data and confidential business information

Confidential business information and confidential test data, as defined in the PCPA, will not be placed in the electronic public registry. Confidential test data will be available to the public in reading rooms upon request in accordance with section 43 of the PCPA whereas confidential business information will not be available to the public.

Since the incident report will be published on the public registry, confidential business information and confidential test data should be provided in an attachment to the report and not in the report itself. It is the responsibility of the registrant to identify confidential business information. Attachments will not be posted on the public registry.

12 COMING INTO FORCE (*section 19 of the IRR*)

These Regulations come into force 6 months after registration (approximately 6 months after approval by Treasury Board). Registrants must report incidents they receive after the Regulations come into force, regardless of when the incident occurred. These Regulations are not retroactive. Registrants are not required to report incidents received before these Regulations come into force although they may do so on a voluntary basis. Incidents that occur before the Regulations come into force but are reported to the registrant after, are required.

13 SCHEDULE

13.1 Definitions of environment symptoms listed in the schedule

Abscission:	shedding of flowers, leaves or fruit.
Bleaching:	whitening of a plant.
Chlorosis:	absence of green pigment in a plant.
Congenital anomalies:	defects observed at birth (example: extra or missing limbs).
Epinasty:	A downward bending of leaves or other plant parts, resulting from excessive growth of the upper side
Flower quality:	colour and shape of blossom, and leaves and stem.
Impairment of health:	negative impact of normal function which leads to a shortened life expectancy and/ or compromised physiological function (example: loss of hearing, mobility, vocalization, immune suppression, etc).
Necrosis:	death of living plant tissue (example: dead leaves (foliage) or flower).
Reproductive impairment:	negative impact on the generation of offspring (example: reduced fertility, reduced number of offspring, morphology of reproductive tissue (ovary, testes), levels of reproductive hormones (estradiol, testosterone).
Terminal bud death:	death of the plant at the developing regions of the leaves (foliage), flower or stem.
Tuber deformation:	altered appearance of a tuber (underground stem).

14 REPORT FORMS

14.1 What format must registrants use to submit incident reports?

Registrants must use the Incident Report form provided by the PMRA when submitting an incident. The forms are available on the PMRA website (www.pmra-arla.gc.ca). See the ‘User Guide for Incident Report Forms’ for instructions on how to fill them in.

14.2 Electronic Reporting

Registrants are required to submit incident reports to the PMRA electronically, either by CD or DVD. Email is also acceptable but it is not considered a secure method.

14.3 Submitting Reports

Reports must be submitted to the PMRA by an **officer** or **employee** of the registrant who is duly authorized to do so.

For purposes of the Pest Control Products Incident Reporting Regulations:

> "officer" means a person who serves in the registrant's or applicant's organization in an executive capacity, such as a President or Chief Executive Officer; and
>
> "employee" means a person, other than an "officer", who serves in the registrant's or applicant's organization.

In addition, "agent" means a person who is not an "officer" or "employee" of the registrant or applicant but is authorized by the registrant or applicant to receive information that the registrant or applicant is required to report in accordance with regulations. Agents should not be submitting incident reports to the PMRA directly.

15 EVALUATION OF INCIDENT REPORTS

15.1 How will incident reports be used by the PMRA?

Essentially, the information reported by registrants will be used to:

- provide an early alert mechanism for health and environmental risks that require investigation and possible corrective action;
- provide post-registration information for prioritizing re-evaluations;
- help validate and, when necessary, improve our pesticide registration process;
- identify trends, e.g. types of pesticides and populations involved, and recommend further investigations and/or corrective action;
- make recommendations to improve agricultural practices (protective clothing, application practices, etc.);
- develop prevention and education programs in collaboration with users and industry;
- improve the quality of product labels;
- provide information to medical communities and the public; and
- initiate a special review if the health or environmental risks are considered unacceptable.

15.2 How will potential health and environmental risks be detected and evaluated?

The PMRA will use trends analysis to identify potential health and environmental risks. Analysis of the IRR data will consider the number of incidents reported for a pesticide, particularly in relation to the amount of pesticide sold.

If a potential risk is identified, the PMRA will evaluate the information provided in the incident reports in conjunction with other relevant information that is available in the scientific literature or the PMRA database. If evaluation of this information identifies a

safety issue, appropriate action will be taken. Such action could range from minor label changes to discontinuation of the product. Caution will be exercised in evaluating incident reports since the data accompanying them may be incomplete and unsubstantiated.

The following criteria will be used to help evaluate potential risks:

- is the effect plausible based on the properties/toxicity of the product;
- is there repetition of effects;
- what is the severity of the incident;
- is the concern relevant to the registered use pattern of the product;
- has the information been considered in a previous PMRA evaluation; and
- does the information indicate that the health or environmental risks or value of the product may no longer be acceptable.

16 PERSONAL INFORMATION

16.1 What is personal information?

According to the *Privacy Act*, personal information is any recorded information that could identify an individual (e.g., race, religion, age, education, SIN, etc.).

16.2 What personal information is prescribed?

Personal information requested on the reporting forms has been limited to city and province (for human subjects) and name of the author of a scientific study. City and province are not considered personal information on their own but, if combined with external sources such as a newspaper article, could be used to identify the individual. Other than this prescribed information, registrants are **NOT** to provide any other personal information on the reporting forms. This includes name of veterinarian or medical doctor that examined the subject, name of the owner of the domestic animal, name of data subject, name of person reporting the incident, etc.

16.3 What are the statutes that cover personal information?

There are three statutes that regulate the use of personal information: *Privacy Act*, *Personal Information Protection and Electronic Documents Act* and *Access to Information Act.*

16.4 Reference links for personal information

Privacy Act:
http://laws.justice.gc.ca/en/P-21/index.html (English)
http://lois.justice.gc.ca/fr/P-21/index.html (French)

Personal Information Protection and Electronic Documents Act (PIPEDA):
http://laws.justice.gc.ca/en/P-8.6/index.html (English)
http://lois.justice.gc.ca/fr/P-8.6/index.html (French)

PIPEDA Regulations Specifying Publicly Available Information:
http://laws.justice.gc.ca/en/P-8.6/SOR-2001-7/index.html (English)
http://lois.justice.gc.ca/fr/P-8.6/DORS-2001-7/index.html (French)
Your Privacy Responsibilities: A Guide for Businesses and Organizations
http://www.privcom.gc.ca/information/guide_e.asp (English)
http://www.privcom.gc.ca/information/guide_f.asp (French)

17 APPENDICES

Appendix A: Human and Domestic Animal Symptoms Classified by Severity

Major Symptoms	Moderate Symptoms	Minor Symptoms
The symptoms listed below are considered to be of major severity.	*In general, the symptoms listed below are considered to be of moderate severity. However, if any of them are life-threatening or result in chronic disability (e.g. if blurred vision or blindness was chronic rather than temporary), they should be classified as major.*	*In general, the symptoms listed below are considered to be of minor severity. However, if any of them require medical treatment or don't resolve rapidly, they should be classified as moderate or major depending on the treatment required or duration of the condition.*
Gastrointestinal System		
Ileus Obstruction of the bowel	Bloody diarrhea Bloody stool Bloody vomit Esophageal stricture Fecal incontinence Hematemesis Injury to esophagus Injury to mouth Melena Pancreatitis Ptyalism Rectal hemorrhage	Abdominal distension Abnormal feces colour Abnormal tongue colour Anorexia Bloating Burning mouth Burning throat Colic Constipation Diarrhea Difficulty swallowing Drooling Dry mouth Dry throat Dysphagia Foaming at mouth Gagging Heartburn Inappetence Inappropriate defecation Inflamation of the mouth Inflamation of the throat Irritated mouth Irritated throat Loss of appetite Nausea Oral hemorrhage Regurgitation Retching Salivating Sore throat Stomach cramps Stomach pain Stomachache Stomatitis Tongue swelling Vomiting Weight loss

Major Symptoms	Moderate Symptoms	Minor Symptoms
Respiratory System		
Acute respiratory distress syndrome (ARDS) Asthma Chronic respiratory disease Cyanosis Pulmonary consolidation Pulmonary edema Pulmonary hemorrhage Respiratory arrest Respiratory failure Wet lungs	Abnormal lung sounds Apnea Bradypnea Bronchitis Bronchoconstriction Bronchospasm Coughing up blood Decreased respiration Fluid in lungs Hemoptysis Inflammation of the lungs Pleural effusion Pneumonia Pneumonitis Respiratory depression Rhonchi Slow breathing Wheezing	Burning lungs Burning nose Burning sinuses Burning throat Chest congestion Choking Coughing Difficulty Breathing Dyspnea Epistaxis Heavy breathing Hyperventilation Inflamation of the mouth Inflamation of the nose Inflamation of the throat Irritated nose Irritated throat Itchy throat Laboured breathing Mouth breathing Nasal congestion Nose bleed Panting Rapid breathing Raspy breathing Respiratory congestion Respiratory irritation Respiratory pain Rhinitis Runny nose Scratchy throat Shortness of breath Sinus pain Sinus pressure Sneezing Sore throat Stuffy nose Tachypnea

Major Symptoms	Moderate Symptoms	Minor Symptoms
Nervous and Muscular Systems		
Cerebrovascular accident (CVA) Coma Intracranial hemorrhage Paralysis Seizure (status epilepticus)	Abasia Abnormal gait Aggressive behaviour Ataxia Bizarre behaviour Carpopedal spasms Collapse Confusion Convulsions Difficulty getting up Difficulty talking Difficulty walking Extensor rigidity Fainting Fasciculations Hallucination Head tilt Hypermetria Incoherent Involuntary muscle movements Lameness Loss of coordination Memory loss Muscle rigidity Muscle trembling Muscle tremors Muscle twitching Opisthotonus Paresis Peripheral neuropathy Rigidity Seizure (single, discrete) Semi comatose Shakiness Slight paralysis Slurred speech Spasm of the hand or feet Staggering Syncope Tetany Trembling Unconsciousness	Abnormal posture Aching Agitation Anxiety Depression Diaphoresis Difficulty concentrating Disorientation Dizziness Dystonia Head shaking Headache Holding tail to side Muscle cramps Muscle pain Muscle spasm Muscle weakness Myalgia Myotonia Numbness Panic Paresthesia Prolonged muscle contraction Recumbent Shaking Skittish Stiffness Sweating Tail twitching Tingling Vertigo

Major Symptoms	Moderate Symptoms	Minor Symptoms
Cardiovascular System		
Bradycardia: heart rate <40 for adults, < 60 infants and children Cardiac arrest Cardiomegaly Cardiovascular instability Shock Stroke Tachycardia: heart rate>180 for adults, >190 infants/children	Arrhythmia Bradycardia: heart rate 40-50 in adults, 60-80 in infants/children Dysrhythmia Fainting Fast heart rate High blood pressure Hypertension Hypotension Irregular heart rate Low blood pressure Slow heart rate Syncope Tachycardia: heart rate=140-180 in adults, 160-190 infants/children	Chest pain Chest tightness Heart murmur Palpitations
Renal System		
Dialysis required Renal failure	Alginuresis Anuria Bilirubinuria Blood in urine Creatinine increased Dysuria Glycosuria Hematuria Hemoglobinuria Kidney pain Lack of control of urination Low urine output Myoglobinuria Oliguria Proteinuria Pyuria Smoky urine Urinary incontinence Urinary retention Painful urination	Frequent urination Increased production of urine Polyuria

Major Symptoms	Moderate Symptoms	Minor Symptoms
Skin		
Cyanosis Icterus Jaundice	Beefy red skin rash on palms and soles Brittle nails, white striations Burns (2nd or 3rd degree) Dead skin tissue Loss of fingernails Loss of skin colour Necrosis Pale mucous membrane colour Pallor Welt Yellow discolouration of skin	Alopecia Bleeding Blister Bruises Bulla Burning skin Burns (superficial) Cracked skin Dermal sensitization Dermatitis Discolouration of the coat Ecchymoses Edema Erosion of the skin Erythema Flushed Hair loss Hives Hyperesthesia Inflammation of the skin Irritated skin Itchy skin Keratosis Lesion Pain Paresthesia Peeling skin Photosensitivity Pruritus Rash Red skin Skin sensitivity Tingling Uticaria

Major Symptoms	Moderate Symptoms	Minor Symptoms
Eye		
Optic atrophy Permanent change in vision Unreactive pupil	Blindness (temporary) Burn on the eye Cloudy eye Corneal abrasion Decreased pupillary light reflex Decreased vision Difficulty focussing Diplopia Double vision Droopy eyelid Inflammation of the cornea Keratitis Nystagmus Ocular hemorrhage Papilledema Ptosis Rapid involuntary movement of the eyeball Yellow sclera	Anisocoria Blepharospasm Bloodshot eye Blurred vision Burning eye Change in field of vision Cloudy vision Conjunctival injection Conjunctivitis Constricted visual fields Contraction of the pupil Dry eye Edema Epiphora Eyelid spasm Foreign body sensation in eye Glazed eye Inflamed conjunctiva Inflammation of the eye Irritated eye Itchy eye Lacrimation Light-sensitive eyes Miosis Mydriasis Pain Photophobia Pinpoint pupils Protrusion of the third eyelid Pupil dilation Red eye Squinting Stare Swollen eye Tearing Watery eye
Ear		
	Hearing loss	Earache Ringing in ear Tinnitus

Major Symptoms	Moderate Symptoms	Minor Symptoms
General		
Neoplasia Icterus Jaundice	Breath odour of bitter almonds Breath odour of peanuts Loss of voice Multiple chemical sensitivity Pale mucous membrane colour	Adipsia Alcohol intolerance Alopecia Bad taste in mouth Breath odour of garlic Breath odour of rotten cabbage Chemical taste in mouth Chills Circling Clingy Crying Dehydration Diaphoresis Discomfort Drowsiness Edema Energy level lower than usual Excessive grooming Excitation Fatigue Fever Flea infestation Flu-like symptoms Forgetfulness Grass ingestion Growling Hair loss Head bobbing Hemorrhage Hesitancy to move Hiding Hissing Hoarseness Hot sensations Hyperactivity Hyperthermia Hypothermia Insomnia Irritable Joint pain Laryngitis Lethargy Licking Lightheadedness Listless Loss of balance Malaise Metallic taste in the mouth Pacing Pain Pica Polydipsia Pyrexia Restlessness Rolling and tumbling

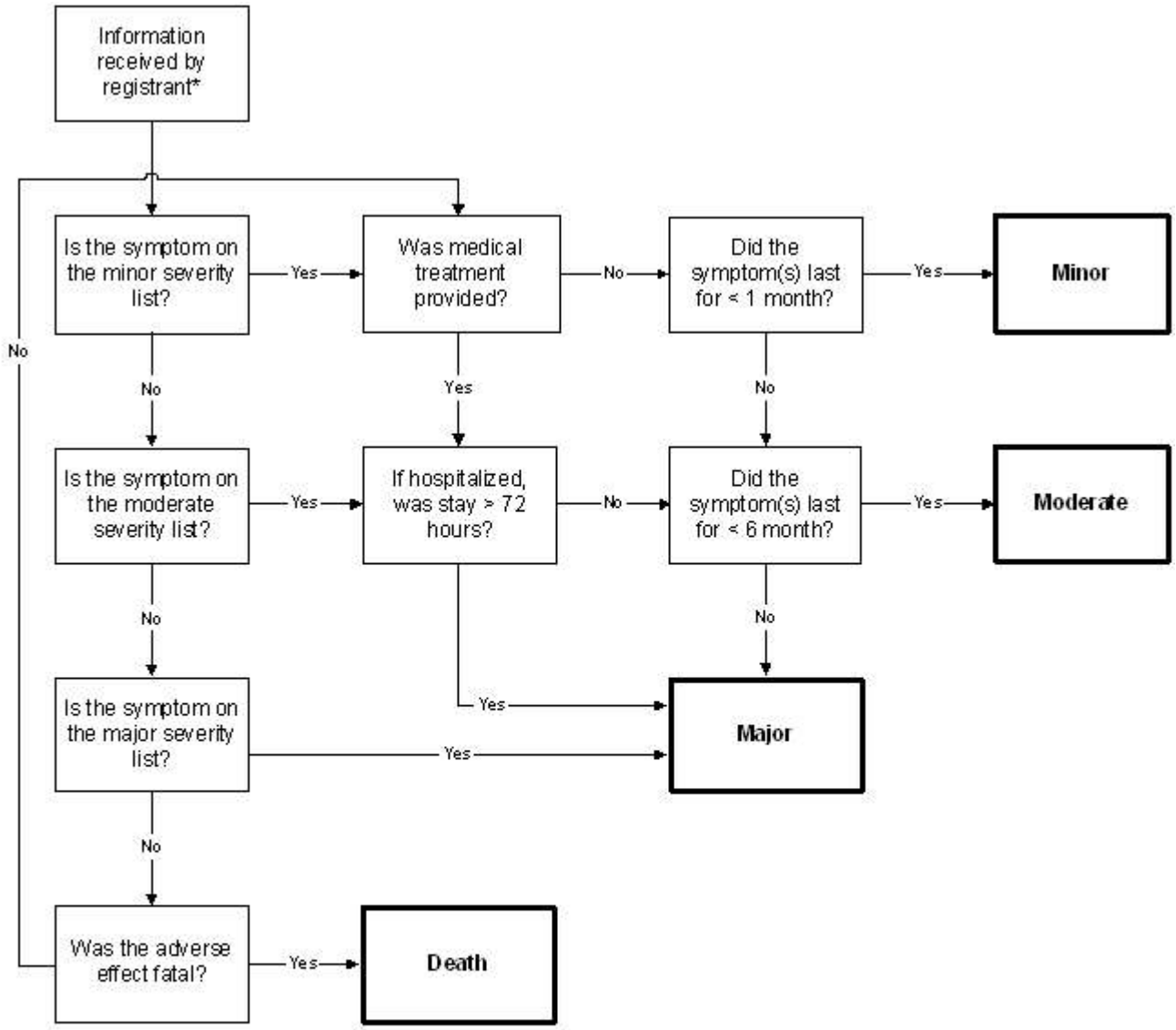
Major Symptoms	Moderate Symptoms	Minor Symptoms
		Rotten egg odour Rubbing face Salty taste in the mouth Sleepiness Soapy taste in the mouth Somnolence Subdued Sweating Sweet taste in the mouth Swelling Thirst Tongue protrusion Tucking tail Vocalizing Weakness
Liver		
Hepatic failure	Bilirubinuria Elevated liver enzymes (e.g. LDH, GOT, GPT, alkaline phosphatase, ALT, AST) Enlargement of the liver Hepatomegaly Hyperbilirubinemia	
Reproductive System		
Birth defect Infertility Low weight at birth Mental retardation at birth Miscarriage Premature birth Spontaneous abortion Stillborn infant	Low sperm count	

Major Symptoms	Moderate Symptoms	Minor Symptoms
Blood		
Hemolysis Hyperkalemia Hypoprothrombinemia	Acidosis Alkalosis Anemia Azotemia Carboxyhemoglobinemia Coagulopathy Cytopenia Decreased acetylcholinesterase enzyme activity Decreased pseudocholinesterase enzyme activity Elevated anion gap Hyperbilirubinemia Hypercalcemia Hyperglycemia Hypernatremia Hyperphosphatemia Hypoalbuminemia Hypocalcemia Hypoglycemia Hypokalemia Hyponatremia Hypoproteinemia Hypoxemia Ketoacidosis Leukocytosis Leukopenia Methemoglobinemia Thrombocytopenia	Bleeding

Source:

1) the "EPA Recognition and Management of Pesticide Poisonings",
2) NIOSH Characteristic Signs and Symptoms for Several Pesticide Active Ingredients and Classes of Pesticides,
3) EPA list of symptoms from reported 6(a)2 incidents,
4) symptoms reported to the California EPA Pesticide Illness Surveillance Program between 1992 and 2004, or
5) pesticide incident data in animals collected by the American Society for the Prevention of Cruelty to Animals (ASPCA) Animal Poison Control Center in 2004.

Appendix B: Decision Tree for the Classification of Incidents Involving Humans or Domestic Animals



*Note: if there are multiple symptoms for an adverse effect, the classification of the adverse effect should be based on the most severe.

Appendix C: Definitions of the animal and plant groups in the Schedule.

Group*	Definition	Examples
Predatory bird	Carnivorous bird of the orders Falconiformes and Strigiformes which feed on meat taken by hunting.	hawks, owls
Birds that flock	A group of birds that live, travel or feed together.	geese, ducks
Songbirds	A bird belonging to the suborder Oscines of Passeriformes, in which the vocal organ is developed in such a way as to produce various sound notes.	finches, swallows
Beneficial insect	Any pest, predator or parasite which functions naturally or as part of an integrated pest management program to control another pest.	parasitic wasp, lacewing
Amphibians	A cold-blooded, smooth-skinned vertebrate of the class Amphibia, that characteristically hatches as an aquatic larva with gills. The larva then transforms into an adult having air-breathing lungs.	frogs, salamanders
Small mammals	Warm-blooded vertebrates (placentals, marsupials, or monotremes) of the class Mammalia characterized by a covering of hair on the skin and, in the female, milk-producing mammary glands for nourishing the young.	bats, mice
Large mammals		fox, deer
Reptiles	Cold-blooded, usually egg-laying vertebrates of the class Reptilia, having an external covering of scales or horny plates and breathing by means of lungs.	snakes, turtles, lizard
Schooling fish	A group of fish that swim together, usually composed of the same species or sub-species.	juvenile fish, salmon during breeding season, carp, threadfin shad
Non-schooling fish		pike, bass
Large aquatic invertebrates	An animal that has no spinal column, a non-vertebrate animal, and that lives in the water.	lobster, mussel
Trees and shrubs	Tree - a large, perennial, woody plant. Shrub - is a horticultural rather than strictly botanical category of woody plant, distinguished from a tree by its multiple stems and lower height, usually less than 6 m tall.	apple tree, oak tree, lilac bush
Herbaceous plant	Any annual or perennial plant with a non-woody stem that dies back to the roots in the winter, and includes turf.	lupine, wildflowers, grasses, strawberries
Aquatic plants	A plant that grows partly or wholly in water whether rooted in the mud, as a lotus, or floating without anchorage, as the water hyacinth.	water lilies, bullrushes

* For the purposes of these Regulations, the plant and animal groups in the Schedule do not include any plants or animals that were the intended target of the pesticide application.

Appendix D: Frequently Asked Questions

Q1. Are registrants required to report incidents they received before the Regulations come into force?

A1. No, they are not required to report to the PMRA any information received **before** the Regulations come into force but may choose to do so on a voluntary basis.

Q2. If an incident occurred before the new Regulations come into force, does it need to be reported to the PMRA?

A2. Yes, if the registrant received the information after the Regulations come into force. If the information was received before the Regulations come into force, they are not required to report.

Q3. Are registrants required to search for information about incidents or are they only required to report information that comes into the possession of an employee?

A3. Registrants are not required to search for information about incidents. They are required to report information that they, including a related corporation, receive. This applies to all incident information, including scientific studies and incidents that occur in the United States.

Q4. Are registrants required to validate or substantiate an incident report before submitting it to the PMRA?

A4. No. Incident reports are, for the most part, only suspected associations. By submitting an incident report, you are contributing to the ongoing collection of safety information that occurs once products are marketed.

Q5. If a registrant submits an incident, will it be interpreted by the PMRA as evidence of causality?

A5. No.

Q6. If one registrant owns a product that has Master Product status and a Master Copy is registered from that Master Product by a different registrant, who is responsible for reporting incidents, the Master Product registrant or the Master Copy registrant?

A6. All registrants are required to report any information about an incident related to their product that they receive regardless of whether they are the registrant of a Master Copy or a Master Product.

Q7. Are incidents required to be reported if the label provided cautionary information of the risks involved, such as eye irritant or effect to non-target plants?

A7. Yes. Any incident described in section 2 of the IRR is required regardless of whether there was a warning on the label.

Q8. If a scientific study, which has already been submitted to the PMRA under the IRR, is subsequently used to support an application for registration, is the study subjected to cost recovery?

A8. Yes.

Q9. How will industry be able to participate in the process?

A9. On each incident reporting form, industry can "provide any explanatory or qualifying information surrounding the incident". In addition to any further details about the incident, this section can also include additional information from the registrant as to why the pesticide was or was not the likely cause of the reported incident. All information in the incident report form, including information provided by industry, will be published on the PMRA website (electronic public registry).

Q10. Who is responsible for reporting incidents related to products used under the Own Use Import (OUI) program?

A10. Registrants, which includes registrants of end-use products and active ingredients, are required to report information about incidents that they receive and that is related to their products. Although end-use products accepted into the OUI program are not registered in Canada, the active ingredient is and the registrant of the active ingredient is required to report information on incidents that they receive. Applicants for the registration of the active ingredient are also required to report information they receive.

Q11. Should incidents of major human adverse effects include debilitating chronic illnesses such as chronic fatigue syndrome, fibromyalgia and multiple chemical sensitivities?

A11. Major effect in a human includes reproductive or developmental effects or any symptom that indicates a condition that could be life-threatening or result in chronic disability.

Q12. Are registrants required to report target crop damage such as phytotoxicity?

A12. No.

Q13. If a domestic animal experiences an incident with symptoms of paralysis and is then euthanised, what would be the severity classification?

A13. It would be classified as major based on the symptoms. On the report form, euthanasia would be recorded as the outcome of the incident.